



December 4, 2020

The Hon. Alex Azar, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: RIN 0991–AC24 Securing Updated and Necessary Statutory Evaluations Timely

Dear Secretary Azar:

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) is a national non-profit organization that advocates on behalf of long-term care consumers across care settings. Our membership consists primarily of consumers of long-term care and services, their families, long-term care ombudsmen, individual advocates, and citizen advocacy groups. Consumer Voice has more than 40 years' experience advocating for quality nursing home care.

Consumer Voice strongly opposes the Department of Health and Human Services (HHS) proposed rule, "Securing Updated and Necessary Statutory Evaluations Timely" (hereinafter referred to as the "Regulations Rule"). The proposed rule would retroactively impose an expiration provision on most HHS regulations and establish "assessment" and "review" procedures to determine which, if any, regulations should be retained or revised. The Regulations Rule is an ill-conceived proposal that would create a tremendous and unnecessary administrative burden for HHS and could have a deleterious impact on programs and regulated entities from Medicaid and Medicare to Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). We urge HHS to immediately withdraw this proposed rule.

The proposed rule would divert resources from critical agency work

HHS asserts that the Regulations Rule will promote "accountability, administrative simplification [and] transparency. . . ." ¹ In fact, the proposed rule would create a significant administrative burden that would divert resources from critical work, including efforts to address the COVID-19 pandemic. HHS itself estimates that the proposed rule would cost nearly \$26 million dollars over 10 years, needing 90 full-time staff positions to

¹ 85 Fed. Reg. 70104.



undertake the required reviews.² Within the first two years, HHS estimates the need to assess at least 12,400 regulations that are over 10 years old.³ However, these estimates likely underestimate the time and money involved in the review process, and do not accurately account for complications that may arise.

The Regulations Rule would adversely affect HHS's ability administer current programs and ensure compliance with the regulations. For instance, staff in the Quality, Safety and Oversight group within CMS are already stretched beyond capacity. Conducting the kind of review proposed in this rule could pull these employees away from their daily responsibilities, thereby weakening and undermining the effective implementation and enforcement of the federal nursing home requirements of participation.

The proposed rule would harm the people HHS is mandated to serve

Perhaps the greatest danger posed by the Regulations Rule is that important regulations may be arbitrarily rescinded because there are simply not enough HHS staff or resources to undertake such a sweeping review process. Regulations that do not complete the complicated and time-consuming review process would summarily expire.

There are many rules that are critically important to the health and welfare of the long-term care consumers whom Consumer Voice represents. For example, the federal requirements of participation for nursing facilities and skilled nursing facilities serve to implement the federal Nursing Home Reform Act. There are numerous ways in which the regulation provides critical and more detailed protections. The regulation: 1) raises the standard of care; 2) includes critical rights that promote and safeguard residents' well-being and safety; and 3) directs nursing home providers on how to put the Nursing Home Reform law into practice

Another example are the rules governing the Long-Term Care Ombudsman Program. The rules improve the ability of the program to effectively advocate for residents of long-term care facilities in several ways. They:

- Ensure the independence of the program to speak up on behalf of residents and to conduct legislative and regulatory advocacy to benefit residents
- Promote consistent, higher quality, and efficient advocacy services
- Contribute to improved resident quality of care and quality of life

² 85 Fed. Reg. 70116.

³ 85 Fed. Reg. 70112. To be specific, HHS states that "because the Department estimates that roughly five regulations on average are part of the same rulemaking, the number of Assessments to perform in the first two years is estimated to be roughly 2,480." *Id.*



The expiration of these rules would have devastating consequences on the care, treatment and lives of residents in both nursing homes and assisted living residences.

Conclusion

The Regulations Rule is simply an attempt to sabotage and destroy duly promulgated regulations, by retroactively imposing an arbitrary end date to duly promulgated regulations. It is unnecessary and will hurt the people that many of the rules are designed to help. Further, the rule will wreak havoc in current HHS programs and tie the hands of the incoming Administration by detracting from critical issues like the COVID-19 pandemic. We strongly oppose this rule, and once again urge HHS to withdraw it immediately.

Consumer Voice thanks HHS for consideration of these comments.

Sincerely,

Lori Smetanka
Executive Director

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Director of Public Policy & Advocacy